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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,313	12/16/2003	Thomas A. Osborne	8627-454	5951
7590	11/14/2005		EXAMINER	
John M. Card BRINKS HOFER GILSON & LIONE P.O. Box 10395 Chicago, IL 60610			REICHLE, KARIN M	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/737,313	Applicant(s) OSBORNE ET AL.	
	Examiner Karin M. Reichle	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/12/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. The status of the parent application should be updated in paragraph 1.

Oath/Declaration

2. Initialed and dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). It is presumed that such changes were known to all the inventors prior to signing.

3. Also it is noted that in the substitute POA filed 4-19-04 it is set forth that a copy of the assignment is attached thereto. However such copy does not appear to have been attached thereto. Also it is noted that the title has not been supplied on page 2 of such POA either.

Specification

Drawings

4. The drawings are objected to because in Figure 2, should the bracket be labeled 10? Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

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drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the invention as claimed in claim 26 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Description

6. The disclosure is objected to because of the following informalities: Paragraph 15 is incomplete. The description of Figure 6 in paragraph 19 is inaccurate, i.e. the view is from the side not the bottom. This also applies to the descriptions of Figures 14 and 18 in paragraphs 27 and 32. In paragraph 45, line 2, "Hid" should be --H2'--. In paragraph 51, " W1' " should be --W1--. In paragraph 61, last line, "45.degree" should be --45 degrees--. In paragraphs 57 (line 9) and paragraph 68 (line 5), "--" should be deleted. What is IRH in Figure 19A?

Appropriate correction is required.

Claim Objections

7. Claims 25-26 are objected to because of the following informalities: in claim 25, line 2, and claim 26, line 1, "surface" should be --planar face--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8 and 10-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsumoto et al '665.

Claims 1 and 4: See Figures, especially 20A-B and 23A-24B, col. 1, lines 6-10, col. 2, lines 20-28, col. 4, line 64-col. 6, line 9, col. 14, lines 29-42, col. 15, line 63-col. 16, line 2 and

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col. 18, lines 12-46 of '665, e.g. '665 teaches a medical instrument 10 comprising a housing 11 and 12 having a passage 14 through which a catheter is received, a valve body, 16, 80, 120, 130, or 140, mounted in the passage, the valve having two opposing planar faces and a peripheral edge separating the faces, see, e.g., Figures 24A-B, the valve body having a first slit, 131 or 132, that opens in one of the faces and a second slit, 132 or 131, that opens in the other face and each slit extends partly through the valve body and intersects the other slit therewithin. As disclosed at the cited portions, the valve body conforms to the outer wall of the catheter when the latter penetrates the intersection of the slits to maintain a fluid tight seal therebetween. The valve body, e.g. 130, has first and second planar dimensions, e.g., the longitudinal dimension and transverse dimension, the latter of which is less than the former when the valve body is unstressed before being mounted in the passage. It is noted that the claim does not require the valve body be stressed after being mounted nor any particular first and second dimension, i.e. it is noted that the circular valve bodies of '665 also have a first dimension, e.g. the diameter, which is larger than a second dimension, i.e. a cross dimension that is not taken at the center.

Claims 2-3: see Figures cited supra.

Claim 5: see, e.g., col. 5, lines 8-14, i.e. the housing has a recess with a dimension between 11 and 12 which is less than the thickness of the valve body which thickness is less than the first planar dimension, i.e. the length or diameter of the valve body. It should also be noted the Figures show the valve disc having the same diameter as the recess and the valve body 130 having at least a length greater than the diameter of the circular valve body.

Claim 6: see discussion of claim 5, i.e. the valve body due to the clamping is compressed

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when the valve body is received within the recess and it is compressed along the first planar dimension, i.e. at least those portions between 11 and 12. Again note that it is not claimed that the compression is along the entire first dimension. However also note the discussion of the valve body 130 supra with respect to claim 5.

Claims 7-8: see Figures 3-4 and 24A-B.

Claims 10-17: see discussion of claims 1-8 supra.

10. Claims 19-20, 22 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller '033.

It is noted that the effective filing date of claims 19-26 is 10-24-95.

Claim 19: See Figures 1 and 8, and col. 2, lines 23-42, and col. 5, line 61-col. 6, line 26 of '033, e.g. '033 teaches a medical instrument 11 comprising a housing 19, 26 having a passage 23 through which a catheter is received, a valve body, 121 mounted in the passage, the valve having two planar faces and a peripheral edge separating the faces, see, e.g., Figure 8, the valve body having a slit, 134, that defines a slit plane extending from a first face, an opening, i.e. from the line above 136 downwards, extending from the second face and partly through the valve body to intersect with the slit therewithin and internal ring 136. As disclosed at the cited portions, the valve body conforms to the outer wall of the catheter when the latter penetrates the slit plane and ring to maintain a fluid tight seal therebetween. The valve body, e.g. 121, has first and second planar dimensions, i.e. the circular valve body has a first dimension, e.g. the diameter, and a second dimension, e.g. a cross dimension that is not taken at the center, the latter of which is less than the former when the valve body is unstressed before being mounted in the

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passage. It is noted that the claim does not require the valve body be stressed after being mounted nor any particular first and second dimension.

Claim 20: see the portions cited supra, i.e. the housing has a recess with a dimension between 28 and 29 which is less than the thickness of the valve body which thickness is less than the first planar dimension, i.e. the length or diameter of the valve body.

Claim 22: see col. 2, lines 30-35.

Claim 25: the portion above the solid line above 136 in Figure 8 which includes 84.

Claim 26: see Figure 8 in which the opening at the solid black line above 136 is larger than that at 137.

11. Claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Behnke et al '034.

It is noted that the effective filing date of claims 19-26 is 10-24-95.

Claim 19: See Figures 3 and 7, and col. 1, lines 5-7, col. 3, lines 19-33 and col. 6, lines 11-48 of '034, e.g. '034 teaches a medical instrument 10A comprising a housing 16A having a passage 20A through which a cannula, i.e. a catheter, is received, a valve body, 22A mounted in the passage, the valve having two planar faces and a peripheral edge separating the faces, see, e.g., Figure 7, the valve body having a slit, 30A, that defines a slit plane extending from a first face, an opening 28A extending from the second face and partly through the valve body to intersect with the slit therewithin and internal ring adjacent 32A. As disclosed at the cited portions, the valve body conforms to the outer wall of the cannula, i.e. the catheter, when the latter penetrates the slit plane and ring to maintain a fluid tight seal therebetween. The valve body, e.g. 121, has first and second planar dimensions, i.e. the circular valve body has a first

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dimension, e.g. the diameter, and a second dimension, e.g. a cross dimension that is not taken at the center, the latter of which is less than the former when the valve body is unstressed before being mounted in the passage. It is noted that the claim does not require the valve body be stressed after being mounted nor any particular first and second dimension. It is also noted that the diameter of the valve body at the first planar face is greater than that at the second planar face, i.e. a first planar dimension greater than a second planar dimension, when the valve body is unstressed.

Claim 20: see the portions cited supra, i.e. the housing has a recess with a diameter which is less than the diameter of the valve body adjacent the first planar face.

Claims 21-22: see the cited portions of '033.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al '665.

Applicants claim the peripheral edge has an oval shape when the valve body is unstressed before being received in the recess, i.e. a shape which is longer along one axis than the other. While '665 does not teach an oval shape, it does teach a shape which is longer along one axis than the other in combination with a circular recess, see Figures 3-4 and 24A-B. Furthermore,

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see paragraphs 42, 66 and 70 and Figures of the instant application, i.e. no disclosure of the criticality of the oval shape over any other shape which has one axis longer than the other axis, e.g. a rectangle or the shape shown in Figures 11-12, i.e. just one of numerous shapes for the purpose of providing a shape having different dimensioned axes, and note that claim 9 does not require the valve body be stressed or compressed (However note the discussion of claims 5-6 supra). Therefore, it would be an obvious matter of design choice to employ an oval rather than a rectangle on the '655 device since such modification would have involved a mere change in the shape of the component. A change in shape is generally recognized as being within the level of ordinary skill in the art, i.e. an oval is just one of numerous configurations a person of ordinary skill in the art would find obvious for the purpose of providing a shape having different dimensioned axes, In re Dailey 149 USPQ 47.

14. Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Behnke et al '034 in view of Thomas et al '463.

Applicant claims the peripheral edge being noncircular when the valve body is unstressed before being received in the recess, and more specifically having an oval shape, i.e. a shape which is longer along one axis than the other. While '034 does not teach an oval shape, it does teach a valve body sized with respect to the recess such that the valve body is compressed about the periphery adjacent the slit to ensure closing of the slit, see cited portions of '034.

Furthermore, see '463 at col. 4, line 31-col. 5, line 12, i.e. interchangeability of a valve body sized with respect to a recess such that the valve body is compressed about the periphery to ensure closing of the slit with a valve body having an oval peripheral edge such that the valve

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body is compressed to ensure closing of the slit. Therefore, to make the valve body of '034 of oval shape instead would be obvious in view of the interchangeability as taught by '463.

Double Patenting

15. Applicant is advised that should claims 1 and 10 be found allowable, claims 4 and 13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

See claim 1, lines 6-10 and similar language in claim 10, and, e.g., paragraph 40, last sentence and compare to claims 4 and 10.

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1, 4-6, 8-10, 13-15, 17-21 and 23-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,663,599. Although the conflicting claims are not identical, they are not patentably distinct from each other because since the claims of the instant application have the same or later

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effective filing date than the claims of the patent, the one-way *In re Vogel* test applies, i.e. are the instant claims obvious in view of the claims of the patent? The answer is yes. The claims of the application are either 1) broader than the claims of the patent (Claims 1, 4-6, 8, 10, 13-15, 17, 19-21, 23 and 25) or 2) both broader and narrower than the claims of the patent (claims 9, 18 and 24). With regard to 1), in essence, once the applicant has received a patent for a species or more specific embodiment, he/she is not entitled to a patent for the generic or broader invention without maintaining common ownership and ensuring that the term of the latter issued patent will expire at the end of the original term of the earlier issued patent. This is because the more specific anticipates the broader. Thus the patented claims anticipate the application claims. See *In re Goodman*, supra. With regard to 2) see also the discussion of 1), supra. Additionally the application claims claim the peripheral edge has an oval shape when the valve body is unstressed before being received in the recess, i.e. a shape which is longer along one axis than the other. While the patent claims do not explicitly teach an oval shape, it does teach a shape which is longer along one axis than the other in combination with a recess which has different dimensions. Furthermore, see paragraphs 42, 66 and 70 and Figures of the instant specification, i.e. no disclosure of the criticality of the oval shape over any other shape which has one axis longer than the other axis, e.g. the shape shown in Figures 11-12, i.e. just one of numerous shapes for the purpose of providing a shape having different dimensioned axes, and note that the application claims do not require the valve body be stressed or compressed in the passage. Therefore, it would be an obvious matter of design choice to employ an oval rather than the shape of the patent claims since such modification would have involved a mere change in the shape of the component. A change in shape is generally recognized as being within the level of

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ordinary skill in the art, i.e. an oval is just one of numerous configurations a person of ordinary skill in the art would find obvious for the purpose of providing a shape having different dimensioned axes, In re Dailey 149 USPQ 47.

18. Claims 2-3, 7, 11-12, 16 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,663,599 as applied to claims 1, 5, 10, 14 and 20, supra, further in view of Matsumoto et al '665. Although the conflicting claims are not identical, they are not patentably distinct from each other because since the claims of the instant application have the same or latter effective filing date than the claims of the patent, the one-way In re Vogel test applies, i.e. are the instant claims obvious in view of the claims of the patent? The answer is yes. The claims of the application further claim the angular relationship between the slits and the recess having a circular cross-section which the patent claims do not specifically recite. However, see '665 at the Figures as well as the cited portions supra, i.e. slits oriented perpendicular or angularly with respect to each other and a recess which has a circular cross section combined with a medical instrument to provide a medical instrument which conforms to the outer wall of the catheter. Therefore to employ a valve body with slits that are perpendicular or angularly oriented with respect to each other and a recess which has a circular cross section in combination with the medical instrument of the patent claims would be obvious to one of ordinary skill in the art in view of the recognition that the combination of such slit orientation and recess configuration with a medical instrument which conforms to the outer wall of a catheter is well known and the patent claims which desire such a medical instrument.

19. Claim 26 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,663,599 as applied to claim 25, *supra*, further in view of Miller '033. Although the conflicting claims are not identical, they are not patentably distinct from each other because since the claims of the instant application have the same or latter effective filing date than the claims of the patent, the one-way In re Vogel test applies, i.e. are the instant claims obvious in view of the claims of the patent? The answer is yes. The claims of the application further claim the opening at the second surface being larger than the opening at the internal ring which the patent claims do not specifically recite. However, see '003, at the Figures, compare element 71 in Figure 7 to element 136 in Figure 8, as well as the cited portions *supra*. Therefore, to make the opening as claimed in patent claims the opening as claimed in the application claims instead would be obvious to one of ordinary skill in the art in view of the interchangeability as taught by '033.

20. Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 7-13 of copending Application No. 11/055,211 in view of Matsumoto '665 and Fischer '113. Although the conflicting claims are not identical, they are not patentably distinct from each other because since the claims of the instant application have the same or latter effective filing date than the claims of the other application, the one-way In re Vogel test applies, i.e. are the instant claims obvious in view of the claims of other application patent? The answer is yes. The claims of the application are both 1) broader than the claims of the other application, e.g. don't claim the dimensions and orientations along various axes as do the other application claims, and 2) narrower than some of the claims of the other application in that the claims require the slits

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intersect each other. With regard to 1), in essence, one the applicant has received a patent for a species or more specific embodiment, he/she is not entitled to a patent for the generic or broader invention without maintaining common ownership and ensuring that the term of the latter issued patent will expire at the end of the original term of the earlier issued patent. This is because the more specific anticipates the broader. Thus the '211 claims anticipate the instant application claims. See *In re Goodman*, supra. With regard to 2), see Figures 3a-3d, 5d, 7 and col. 5, lines 55-60 of '113, i.e. interchangeability of two nonparallel slits which intersect each other with two slits which do not intersect instead and the slits, and Figures of '665, i.e. interchangeability of slits along diameter axis in a circular valve body with slits along axes of valve body having a shape which is longer along one axis than the other. Therefore to make the slits of '211 the instantly claimed slits instead would be obvious to one of ordinary skill in the art in view of the interchangeability as taught by '113 and '665.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion


21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Other prior art, cited by Examiner and Applicant but not applied, also teaches at least some of the disclosed and claimed features.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Karin M. Reichle
Primary Examiner
Art Unit 3761

KMR
November 2, 2005